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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,997	02/19/2004	Anandi Krishnan	12895/46001	5325
26646	7590	06/03/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			COTTON, ABIGAIL MANDA	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,997

Applicant(s)

KRISHNAN ET AL.

Examiner

Abigail M. Cotton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/14/2005, 12/23/2004, 12/16/2004, 6/14/2004, 2/19/2004
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 16 and 18-19, drawn to a pharmaceutical composition having non-spherical granules, and having an antifungal active pharmaceutical ingredient, a bulking agent, a disintegrant, a binding agent and an acid, classified in class 424, subclass 489, for example.
- II. Claims 15, 17, 20, 29, 43, 45 and 48, drawn to a method of treatment of fungal infections by administering a dosage form having the pharmaceutical composition having an active antifungal agent, and other ingredients such as a bulking agent, a disintegrant, a binding agent and an acid, classified in class 424, subclass 489, for example.
- III. Claims 21-28, 30-42, 44 and 46-47, drawn to a method of preparing a pharmaceutical dosage form having non-spherical granules, by dissolving an antifungal active pharmaceutical ingredient in an alcohol, acid and water, and mixing in other ingredients such as bulking agent, binding agents, and disintegrants, classified in class 424, subclass 498, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product could be used in a materially different process, such as for example as an ingredient held in an antifungal sachet or embedded in an antifungal clothing item.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I and II may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group I, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Group II. Conversely, in searching Group II, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed may be made by

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another and materially different process, such as for example by dissolving in a solvent composition other than the claimed solvent comprising alcohol, acid and water, such as for example alcohol or acid alone, or a different solvent such as DMSO.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I and III may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group I, the Examiner will be focusing on the patentability of the product itself, and not the process of making of Group III. Conversely, in searching Group III, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because Group II is to a method of treating using a pharmaceutical composition, and Group III is to a method of preparing a pharmaceutical composition. Thus, the methods have different functions and effects. The inventions are also not disclosed as capable of use together, because the steps involved in the process of making and the process of using the pharmaceutical are temporally separated. That is, the steps of treating with the

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pharmaceutical composition are not taught has being performed for the purpose of preparing the composition, and vice versa.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups II and III may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group II, the Examiner will be focusing on the patentability of the process of treating itself, and not the process of preparing of Group III. Conversely, in searching Group III, the Examiner will be focusing on the patentability of the process of preparing and not the process of treating itself. Accordingly, a search for both groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Upon election of Group I, II or III, Applicant is further required to elect a single species from among the following disclosed patentably distinct species of the claimed invention:

- 1) a single antifungal active pharmaceutical ingredient, e.g. itraconazole, saperconazole, ketoconazole;
- 2) a single bulking agent, e.g. mannitol, microcrystalline cellulose;
- 3) a single disintegrant, e.g.. croscarmellose sodium or a mixture of croscarmellose sodium and crospovidone;
- 4) a single binding agent, e.g. polyvinyl pyrrolidone; and
- 5) a single acid, e.g. hydrochloric acid.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 and 21-43 are generic to Species 1, claims 1-35 and 37-45 are generic to Species 2, claims 1-5, 7-15, 21-37 and 39-45 are generic to Species 3, claims 1-15 and 21-43 are generic to Species 4, and claims 1-7, 9-15, 21-24, 26-33 and 35-43 are generic to Species 5.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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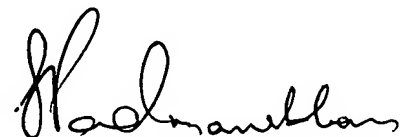
Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER